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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,511	12/17/2003	Takeshi Kushiku	US-112	6183
38108	7590	03/17/2006	EXAMINER	
CERMAK & KENEALY LLP ACS LLC 515 EAST BRADDOCK ROAD SUITE B ALEXANDRIA, VA 22314			EWALD, MARIA VERONICA	
			ART UNIT	PAPER NUMBER
			1722	
DATE MAILED: 03/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/736,511

Applicant(s)

KUSHIKU ET AL.

Examiner

Maria Veronica D. Ewald

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 20-27 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance: See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/04&6/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

13. Applicant's election with traverse of claims 18 – 27 in the reply filed on September 21, 2005 is acknowledged. The traversal is on the ground(s) that the claims in their entirety do not pose a burden on the Examiner, if searched altogether. This is not found persuasive because as stated in the restriction election, the lysine crystal can be made via drop tray crystallization and as such; the process and product are given separate status in the art (MPEP j 806.05(f)). Furthermore, a search for the lysine crystal itself does *not* necessarily include a search for the process as well. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Allowable Subject Matter

14. Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 19, is indicated as allowable, since prior art does not show a diL-lysine monosulfate trihydrate crystal having peaks at diffraction angles 2θ of 16.6° and 17.0° in powder X-ray diffraction.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 24 – 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Because Applicant elected claims 18 – 27, claims 1 – 17 are withdrawn from consideration, therefore, claims 25 – 27 are deemed indefinite since they refer back to claims 1, 7 and 12 respectively, and thus, are not further treated on the merits.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 20 – 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hasegawa, et al. (U.S. 6,329,548). Hasegawa, et al. teach a diL-lysine monosulfate trihydrate crystal produced by the process of mixing a lysine-based solution with sulfuric acid at a temperature of between approximately -10°C and approximately 35°C , and allowing said crystal to form (column 3, lines 50 – 57; column 5, lines 55 – 60) and recovering said diL-lysine monosulfate trihydrate crystal (column 5, lines 1 – 20). Furthermore, the said temperature is between approximately 0°C and approximately 20°C , wherein said temperature is approximately 10°C (column 6, lines 15 – 25; column 9, lines 5 – 20).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada, et al. (J. Agr. Food Chem., 1973) in view of Takayanagi, et al. (U.S. 4,256,917). Yamada, et al. teach that synthetic diL-lysine itself and its ordinary salts such as mono- or dihydrochloride, sulfate, nitrate and acetate form racemic compounds (pg. 890); however, Yamada, et al. do not specifically teach that a diL-lysine monosulfate trihydrate crystal is formed.

In a method to prepare anhydrous L-lysine monohydrochloride in crystalline form, Takayanagi, et al. teach that in general, producing anhydrous crystals comprises concentration of a solution of L-lysine monohydrochloride followed by cooling to yield the dihydrate crystals, and subsequent drying to produce the anhydrate crystals (column 1, lines 20 – 30). Though not specifically teaching the use of a lysine sulfate salt, the monohydrochloride salt is an ordinary lysine salt, like the lysine sulfate salt. As stated above, Yamada, et al. teach that the salt form can be produced by mixing a lysine-based solution with a ordinary or straight-chain acid to produce the lysine salt compound.

Therefore, it would have been obvious at the time of the Applicant's invention to one of ordinary skill in the art to produce the sulfate trihydrate compound of Yamada, et

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al. via the method of Takayanagi, et al. to produce a diL-lysine monosulfate trihydrate crystal.

Claims 23 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasegawa, et al. in view of Yamada, et al. Hasegawa, et al. teach the characteristics previously described but do not implicitly state that the lysine crystals are recovered by filtration.

In a method to produce DL-lysine and its ordinary salt compounds, Yamada, et al. teach that the lysine salt is mixed with water and stirred vigorously. The produced crystals are then recovered via filtration and dried (pg. 891). This reads on the Applicant's claims that the crystals are recovered via filtration from the group consisting of suction filtration, centrifugal filtration centrifugal separation and press filtration.

Therefore, it would have been obvious at the time of the Applicant's invention to one of ordinary skill in the art to implement the filtration method of Yamada, et al. to effectively recover the lysine salt crystals formed via the teaching of Hasegawa, et al.

Conclusion

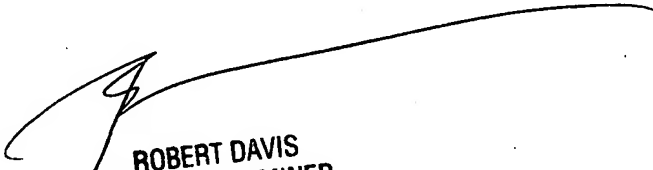
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Veronica D. Ewald whose telephone number is 571-272-8519. The examiner can normally be reached on M-F, 8 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Duane Smith can be reached on 571-272-1166. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MVE


ROBERT DAVIS
PRIMARY EXAMINER
GROUP 1300

1200
3/15/06